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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,840	03/12/2004	Dale R. Burns	065691-0352	5029
22428	7590	01/27/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			ROBINSON, KEITH O NEAL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,840

Applicant(s)

BURNS ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>July 28, 2004</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on July 7, 1995. It is noted, however, that applicant has not filed a certified copy of the 9513881.4 application as required by 35 U.S.C. 119(b).

Specification Objections

2. The disclosure is objected to because of the following informalities: Table 5 is missing in the specification, or the tables have been mis-numbered. Applicant is advised not to enter New Matter into the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, step (a), the word "particularly" renders the claim indefinite because it is unclear whether the limitation(s) following the word are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 1, step (c), the meaning of the phrase "the absence of levels of progoitrin and gluconasin glucosinolate" is unclear because it appears that the claim is stating that levels of glucosinolate are to be tested, but are absent simultaneously.

Step (d) of claim 1, uses the phrase "negative for elevated glucosinolate production relative to the corresponding fertile parent". This phrase is confusing because it is unclear how elevated glucosinolate production can be measured in negative terms.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is broadly drawn to a method of producing a restorer line of Brassica having substantially the same glucosinolate level as a corresponding fertile parent for use in an ogura cytoplasmic male sterility system.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation

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necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The specification does not provide any guidance regarding the broad genus of Brassica restorer lines nor is there any guidance regarding the broad genus of the corresponding fertile parent.

The specification only provides guidance regarding the Brassica napus restorer line, RF (see page 7, lines 9-18). The specification states that the RF lines are "crossed by spring lines [that] tested high for aliphatic glucosinolate" (see page 7, lines 20-21); however, there is no guidance regarding these lines.

The specification fails to provide any guidance regarding the broad genus of Raphanus sativus restorer genes.

The specification only provides guidance for restorer line KH where it states "[t]he restorer gene source KH for the line was a BC1 plant of the original restorer source from INRA" (see page 9, lines 6-7) and "only plants descended from KH... were again low GSL" (see page 12, lines 5-7).

The specification only provides guidance on how to test for glucosinolate (see page 13, line 7 to page 14, line 24). The specification fails to disclose how to determine a Brassica napus line which contains a Raphanus sativus restorer gene wherein said line has canola quality levels of glucosinolate from other Brassica napus lines.

The specification fails to provide guidance regarding the testing of double haploid progeny for fertility indicating the *Raphanus sativus* restorer gene is present and for levels of glucosinolate wherein the absence of levels of progoitrin and gluconasin glucosinolate and overall glucosinolate production.

The specification only states “[a] source of the improved restorer gene was crossed to improved germplasm [and that] [t]he resulting hybrids...underwent microspore culture to produce doubled haploid restorer line” (see page 17, 9-12), but fails to disclose how to test for the presence of the *Raphanus sativus* restorer gene or levels of glucosinolate.

The specification fails to provide guidance for methods of distinguishing between *Brassica napus* glucosinolate genes and *Raphanus sativus* glucosinolate genes or for distinguishing between *Brassica napus* glucosinolate production and *Raphanus sativus* glucosinolate production. Mapping experiments have shown that in *Brassica napus* there are 5-6 unlinked loci involved in glucosinolate production (Magrath et al. Plant Breeding 111: 55-72, 1993, see abstract and Toroser et al. Theor. Appl. Genet. 91: 802-808, 1995, see abstract).

Methods of producing a restorer line of *Brassica* having substantially the same glucosinolate level as a corresponding fertile parent for use in an ogura cytoplasmic male sterility system is unpredictable.

The specification discloses that unexpected segregation ratios can occur, suggesting that low glucosinolate restoration is controlled by more than a single

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dominant gene or that the *Raphanus sativus* material is not well integrated into the genome (see page 18, lines 1-19; also see page 20, lines 11-23).

The specification discloses that abnormal characteristics can occur in fertile plants which may be caused by the genetic influence by the male (see page 19, lines 3-6) and that mis-classification can occur (see page 19, lines 8-11).

The specification discloses that changes in levels of individual glucosinolates can occur due to environmental factors (see page 22, lines 2-5).

Given the lack the claim breadth, unpredictability, and lack of guidance as discussed above, undue trial and error experimentation would have been required by one skilled in the art to develop a method of producing a restorer line of Brassica having substantially the same glucosinolate level as a corresponding fertile parent for use in an ogura cytoplasmic male sterility system.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Delourme et al (Theor. Appl. Genet. 88: 741-748, 1994), in view of Henderson et al (Theor. Appl. Genet. 83: 476-479, 1992).

The claim reads on a method of producing a restorer line of Brassica having substantially the same glucosinolate level as a corresponding fertile parent for use in an ogura cytoplasmic male sterility system comprising selecting a fertile parent with microspores comprising a gene restorer line of Brassica napus which contains a Raphanus sativus restorer gene, culturing selected microspores forming haploids and inducing double haploids, testing the double haploid progeny for fertility indicating the Raphanus sativus restorer gene is present and for levels of glucosinolate, and selecting progeny which are positive for the presence of said restorer gene and negative for elevated glucosinolate production.

Delourme et al teach Brassica napus lines which contain a Raphanus sativus restorer gene, wherein said lines were produced through protoplast fusion, testing of plants for the restorer gene and the selection of progeny which are positive for the presence of a restorer gene (see pages 742, first column, third paragraph and page 743, Table 1).

Delourme et al do not teach culturing microspores forming haploids and inducing double haploids.

Henderson et al teach the culturing of microspores forming haploids and inducing double haploids in Brassica napus plants (see page 477, first column, paragraphs 2-4)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the teachings of Delourme et al and Henderson et al to produce a method of producing a restorer line of Brassica having certain glucosinolate levels.

One of ordinary skill in the art would have been motivated to combine these teachings because Delourme et al teach that good female fertility has been obtained in restorer material used in Brassica cytoplasmic male sterility (see page 741, second column, first paragraph).

In addition, one of ordinary skill in the art would have a reasonable expectation of success based on the success of Delourme et al in using a restorer line of Brassica in the identification of markers linked to fertility restorer genes for the Ogura radish cytoplasmic male sterility.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is

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571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

January 19, 2006

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written in a cursive style.